



# EVALUATION OF GENOMIC APPLICATIONS IN PRACTICE AND PREVENTION (EGAPP)

## WHAT IS THE PUBLIC HEALTH ISSUE?

- The success of the Human Genome Project has led to increasingly rapid translation of genomic information into clinical applications. Most of the more than 900 genetic tests available for clinical testing are used for diagnosis of relatively rare single-gene disorders, but a growing number have population-based applications and the potential for broad public health impact.
- Issues raised about genetic testing include the need to develop evidence to establish efficacy and cost-effectiveness before tests are commercialized. Increasing demand for new applications of genomic technology creates an urgent need for timely and reliable information that allows health-care providers and consumers to use tests appropriately.
- Recommendations for developing and overseeing safe and effective genetic tests have been made by expert panels such as the NIH-DOE Task Force on Genetic Testing and the HHS Secretary's Advisory Committee on Genetic Testing (SACGT). However, a coordinated approach for the effective translation of genomic applications into clinical practice and health policy is needed.

## WHAT HAS CDC ACCOMPLISHED?

In FY05, CDC launched a new initiative—a 3-year model project entitled Evaluation of Genomic Applications in Practice and Prevention (EGAPP). The EGAPP Project aims to develop and evaluate a coordinated, systematic process for assessing genomic applications (i.e., genetic tests) in transition from research to clinical and public health practice. A CDC-wide and HHS interagency Steering Committee provided early guidance and will consider how to use the knowledge gained by the project to develop a sustainable evaluation process. An independent, non-federal, multidisciplinary EGAPP Working Group was established. The roles of this 13-member panel are to prioritize and select genomic applications for evaluation, establish methods and process, monitor expert and peer review of commissioned evidence reports, and develop conclusions and recommendations based on the evidence.

## WHAT ARE THE NEXT STEPS?

The Working Group has developed methods and criteria for topic selection and commissioned evidence reviews on four topics. Dissemination of evidence reports and recommendations is expected to begin in fall 2006. Potential topics for review in 2006 are being solicited and considered. Other EGAPP activities include continuing engagement of stakeholders and a comprehensive evaluation of the value and impact of the project's processes and products.